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Patent
Attorney Docket No.GEMS8081.092

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	: Vu, Anthony T.
Serial No.	: 09/682,366
Filed	: August 24, 2001
For	: Real-Time Localization, Monitoring, Triggering And Acquisition of 3D MRI
Group Art No.	: 3737
Examiner	: Shaw, S.

CERTIFICATION UNDER 37 CFR 1.8(a) and 1.10

I hereby certify that, on the date shown below, this correspondence is being:

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37 CFR 1.8(a)
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37 CFR 1.10
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■ transmitted by facsimile to Fax No.: 703-872-9306 addressed to Examiner Shaw at the Patent and Trademark Office.

Date: 9-2-04

Signature

DECLARATION UNDER 37 C.F.R. §1.131

I, Anthony T. Vu, being duly sworn, depose and say:

1. That I am the inventor for the above-identified Patent Application;

2. That I have reviewed the claims of this Application;

3. That I conceived in the United States, prior to February 22, 2001, the effective date of the cited reference, USP 6,459,264, the invention as set forth in the aforementioned claims, and in particular, a technique of MR acquisition in which a 3D imaging volume is prescribed and a pulse sequence that is applicable as a 3D pulse sequence with slice encoding and rewinder gradients disabled in one dimension is applied. Two-dimensional MR data is then acquired to localize the 3D imaging volume. The disabled slice encoding and rewinder gradients

are then enabled followed by application of the pulse sequence in three dimensions to acquire 3D MR data of the 3D imaging volume.

4. Attached as Exhibited A is a copy of my "GE Medical Systems Invention Disclosure Sheet" setting forth particulars of the claimed invention and including evidence that I conceived of the invention prior to February 22, 2001.

5. That from prior to February 22, 2001, to August 24, 2001, the filing date of the above-referenced Patent Application, I diligently worked toward reducing the aforementioned invention to practice and worked with patent counsel in the preparation of a patent application for the claimed invention.

That the statements made herein are of my own knowledge and are true and made on information and belief that are believed to be true.

I acknowledge that any willful false statements and the like made herein are punishable by fine or imprisonment, or both, and may jeopardize the validity of the application or any patent issuing thereon.

/Anthony T. Vu/ Dated: 8/20/04

Anthony T. Vu

GE Medical Systems
Invention Disclosure Form

3000 North Grandview Blvd., W-710
P.O. Box 414, Waukesha WI 53188
(262) 544-3028; Dialcom: 8*320-3028

Docket No.: [redacted]

Mail to: PATENT OPERATION, W-710

Date Received:

- **Use as many pages in this word document as necessary.**
- **You may attach additional materials to support this disclosure, for example, Tech Notes and Drawings Such submitted materials must be referenced in this disclosure form. Each page of these material must be dated, signed and witnessed in the same manner as this invention disclosure.**

MODALITY: *(e.g., CT, MR, Ultrasound, X-Ray)*

MR

INVENTION TITLE: *Provide a unique, descriptive title. If you write this disclosure in a language other than English please provide a title in English as well. Si vous rédigez en français, merci de proposer un titre en anglais et un titre e français.*

Method for real-time monitoring, triggering and acquisition of contrast-enhanced MRI studies relative to the arrival o contrast agent using 3D real-time interactive imaging.

PROBLEM/BACKGROUND: *Describe the problem that is solved by the invention. Assume that the reader has a basi knowledge of your diagnostic imaging modality and related technologies.*

Contrast-enhanced 3DMRA (ce3DMRA) is now routinely used in clinical practice for imaging of the aorta, carotid arteries peripheral arteries, portal and systemic veins. The concept behind ce3DMRA is simple: shorten the T1 relaxation time o blood as much as possible during a volumetric data acquisition. It is desirable to reduce the T1 relaxation time of blood to a value ~ 20 ms. Blood with such a short T1 will appear bright when imaged with a very short TR ~ 5ms, whereas all othe tissues including fat appear dark. The imaging pulse sequence typically used is a spoiled 3D gradient-echo sequence (3DSPGR) with a very short TR and TE. A typical sequence parameters are TR/TE/flip angle = 4.5ms/1.5ms/45 degrees Slice thickness usually is on the order of 1-3 mm. Scan time can range from as little as 10 seconds for carotid MRA to as long as 30 seconds for high resolution MRA of the peripheral arteries. Near perfect contrast agent bolus timing is crucial to ensure that the maximum arterial phase occurs during the middle of the acquisition, when central k-space data are acquired. It is also essential that contrast concentration does not change too rapidly to minimize "ringing" artifact. Bolus timing is difficult because the time required for the contrast agent bolus to travel from the injection site (typically a vein) to the artery being imaged is highly variable. For renal arteries, it may be only 10 seconds in a young, healthy person, or it may be as long as 50 seconds in an older patient with congestive heart failure. **The relative timing of contrast agent administration and data acquisition is extremely important in order to ensure a consistent quality for MRA.** There are several methods in use to determine this relative timing: manual test bolus or automated bolus detection (i.e. **GE SmartPrep**). Both methods presently are **neither robust** nor **reliable enough** over a wide range of patient population. A potentially more reliable method is known as MR fluoroscopy [1] where a **separate** 2D imaging pulse sequence is used to monitor the arrival of the contrast and switched to a high resolution 3D imaging pulse sequence to acquire the central k-space during the peak concentration of the arterial phase. Due to the complexity of implementing the 2D/3D switching and acquisition (required specialized hardware/software), MR fluoroscopy has not been widely used or offered as a product by any manufacturers currently.

INVENTORS *(Print or Type Name Below)*	*(Full Signature Below)*	GE	NOT GE	DATE
* Anthony T. Vu	Anthony T. Vu	X		[redacted]

* = Primary Contact Inventor (to coordinate with Patent Evaluation Board and Preparing Attorney)

Read and Understood By:

2 WITNESSES (Mandatory) *(Print or Type Name Below)*	*(Full Signature Below)*	DATE
Samuel Vinod Baskaran		[redacted]
Anila Lingamneni	Anila Lingamneni	

GE Medical Systems Invention Disclosure Form

INVENTION DESCRIPTION: *Describe how the invention works and how it solves the problem posed above.*

This invention describes a novel method which provides a techniques for detecting the arrival of the contrast bolus in the region of interest, using **real-time interactive 3D imaging.** This method offers real-time continuous monitoring of the bolus of contrast agent and the triggering of the high-resolution ce3DMRA acquisition using the **same 3D imaging pulse sequence.**

Figure 1 shows a standard 3D SPGR imaging pulse sequence that is typically used to acquire ce3DMRA with the R_1, R_2, R_3, P_1, P_2, S_1, S_2, S_3, S_4, S_5 gradients for read, phase and slice direction, respectively. P_1 and P_2 are the phase-encoding and rewinder gradients, and S_3 and S_4 are the slice-encoding and rewinder gradients, respectively. The imaging pulse sequence in Figure 1 can be implemented to operate in a continuous real-time mode where interactive navigation and imaging parameters modification are allowed (using real-time interactive imaging framework such as **iDrivePro**). Furthermore, the 3D imaging pulse sequence in Figure 1 can be **reconfigured in real-time to operate (or function)** as a 2D SPGR imaging pulse sequence simply by turning off both S_3 and S_4 gradients as shown in Figure 2. The 2D SPGR imaging pulse sequence in Figure 2 is capable of imaging a thick slab (or slice) equivalent to the 3D volume slab thickness (i.e. slice thickness * number of slices). The 2D slab thickness can be changed in real-time to improve contrast bolus visualization by varying the S_1 gradient amplitude interactively. Typically a slice thickness of 20 mm is desirable for optimal monitoring of contrast agent so S_1 gradient should be shaped such that it can accommodate a selective excitation of a thinner volume (than the original 3D volume) without exceeding hardware capability. Traveling spatial saturation capability can also be included and can be switched on/off in real-time to remove the contribution of blood vessels due to time-of-flight effect. In addition, FOV and flip angle can be modified in real-time mode for further monitoring flexibility. The real-time monitoring images using the 2D imaging pulse sequence in Figure 2 are of the same **high (in-plane) resolution** as the prescribed 3D imaging volume while still maintaining an acceptable frame rate. Alternatively, the 2D images in-plane resolution can be adjusted interactively to monitor at a higher frame rate (up to 10 fps) at the expense of lower in-plane resolution.

A real-time continuous scan loop plays out the imaging pulse sequence in Figure 2 prior to the contrast injection. This real-time process is repeatedly continuously during the administration of the contrast agent to the patient. The acquired images of the monitor station are displayed continuously in the real-time display view port. When the real-time 2D images show significant amount of changes in vascular signal intensity due to the arrival of the contrast bolus, the acquisition of high resolution ce3DMRA data is performed either manually by the operator or automatically by the detection algorithm to immediately switch operating modes from the real-time continuous 2D scan loop to play out the 3D imaging pulse sequence of Figure 1 (**switching time can be as fast as 100 ms**). If a delay period after the detection of the arrival of the bolus (before 3D imaging triggering) is desirable, it can also be prescribed in real-time (i.e. for breath-held preparation purpose). Figure 3 demonstrates the operational flow chart of the 3D real-time interactive imaging method for monitoring, triggering and acquisition of multiple 3D imaging volumes such as in the case of peripheral vascular run-off studies. The 3D imaging pulse sequence adaptively switches back and forth between 2D monitor and 3D acquisition mode for each of the prescribed 3D imaging volume. As in the single station case, switching can be done manually by human operator or automatically by advance detection algorithm.

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* Anthony T. Vu	Anthony T. Vu	X		[redacted]

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2 WITNESSES (Mandatory) *(Print or Type Name Below)*	*(Full Signature Below)*	DATE
Samuel Vinod Baskaran		[redacted]
Anila Lingamneni	Anila Lingamneni	[redacted]

GE Medical Systems Invention Disclosure Form

DRAWING: *Make as accurate a sketch or computer generated figure of your invention as you can and embed it into or attach it to this form. It need not be a drawing to scale, but should be complete enough to show what you have in mind. If you already have suitable photographs, sketches, software flowcharts or finished drawings, they may be used.*

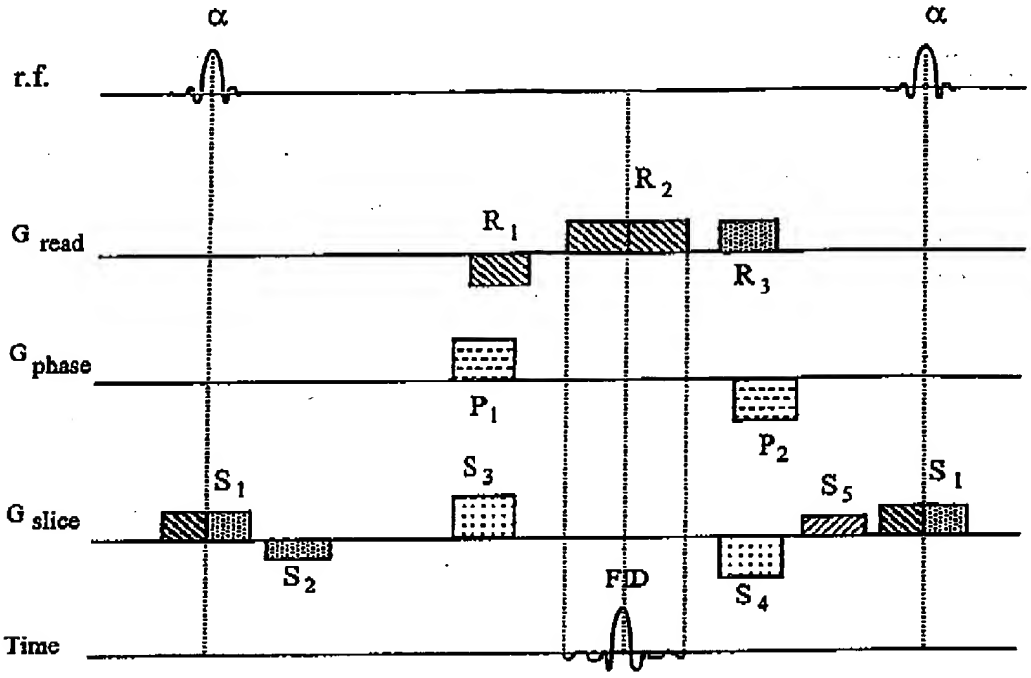

Figure 1. Typical 3D SPGR imaging pulse sequence used for high-resolution ce3DMRA data acquisition.

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Anila Lingamneni	Anila Lingamneni	[redacted]

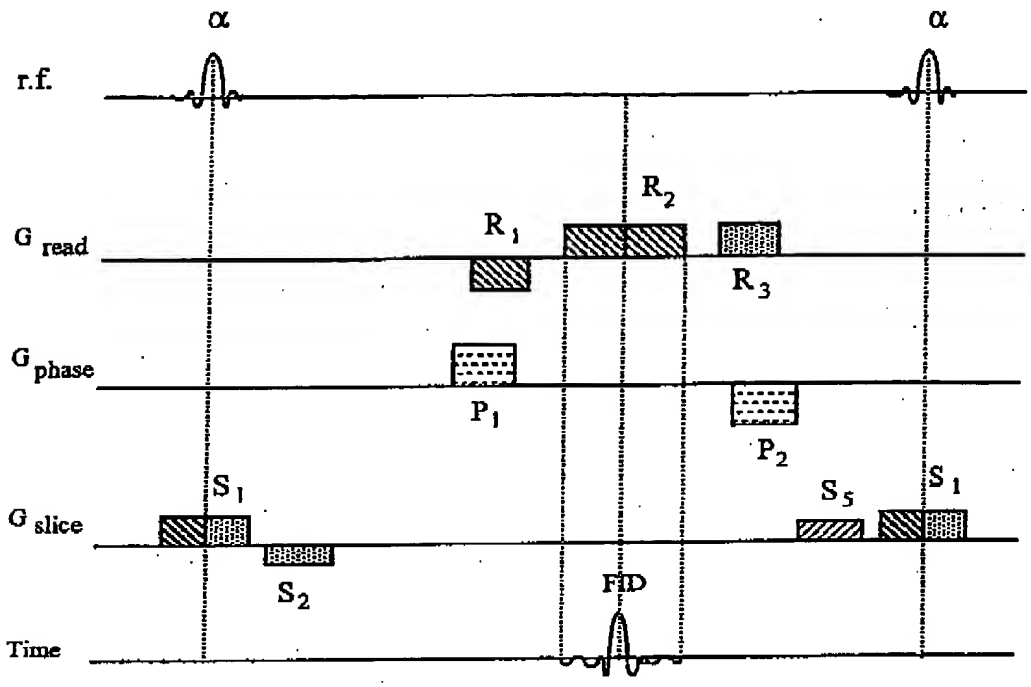

Figure 2. 2D SPGR imaging pulse sequence derived from the 3D SPGR imaging pulse sequence in Figure 1 by turning off both the S_3 and S_4 gradient.

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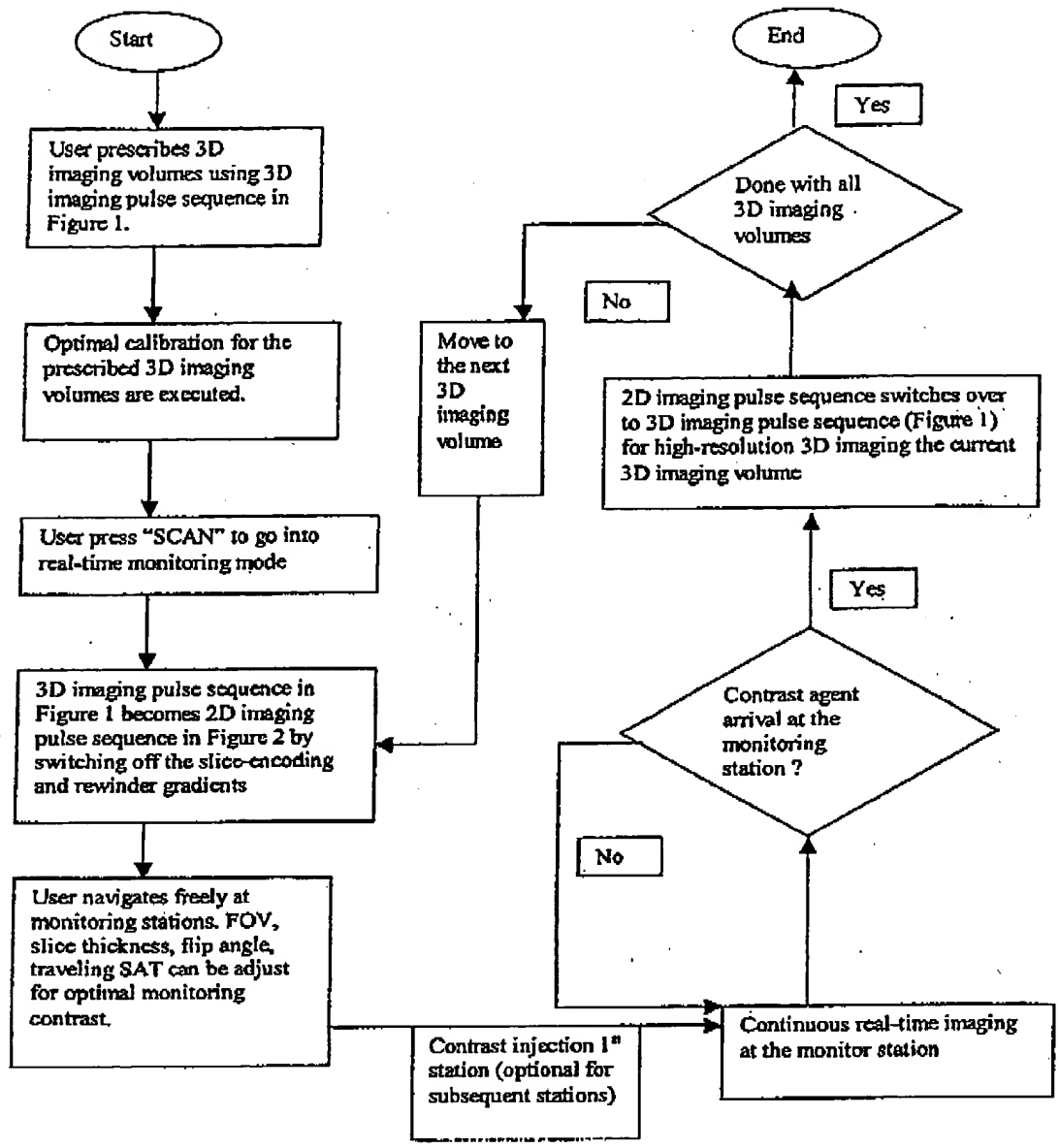

Figure 3. Operational flow chart for 3D real-time interactive monitoring , triggering and acquisition of multiple 3D imaging stations.

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Anila Lingamneni		[redacted]

GE Medical Systems Invention Disclosure Form

ADVANTAGES OF THE INVENTION: *Describe the benefits of the invention, both in technical terms (e.g., stronger, new application, faster imaging, etc.) and business terms (e.g., cost savings, product efficiency, etc.).*

[redacted]

PRIOR ART: *List all references to previous work that you have identified that relate to the invention (if any). Example would be existing patents (whether GE or other) possibly identified via patent searches, GEMS invention disclosures i process or otherwise, existing products, publications, internal publications, or Tech Notes etc. All identified prior ar references must be attached to this disclosure, but those pages need not be signed.*

[redacted]

CLAIM OF NOVELTY: *Describe what is novel, unique, non-obvious about this invention compared to previous designs or solutions identified in the Problem/Background or Prior Art sections. "Obvious" is defined with respect to an individual with an average working knowledge of the general area. Be careful: what is obvious to you, as a specialist, may not be obvious to someone with an average working knowledge. You should err on the side of assuming that your invention is non-obvious.*

[redacted]

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Anila Lingamneni	Anila Lingamneni	[redacted]

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Anila Lingamneni	Anila Lingamneni	[redacted]

SUMMARY QUESTIONS FOR INVENTION DISCLOSURE

(The answers to these questions will help the modality PEB with the patent filing decisions they make.)

1) **DESCRIBE ANY RECENT WORK ON DEVELOPING AND DEMONSTRATING THE IDEA AT GEMS.** *H feasibility been proven? How? Is there a prototype?*

Feasibility has been carried out and proven about six months ago. The latest prototype based on efgre3d PSD includes all t capability outlined above namely real-time 2D/3D switching, real-time interactive navigation, real-time imaging parametc modification (FOV, slice thickness, flip angle etc). Several demos to Marketing and Engineering colleagues have be performed to demonstrate the working prototype and the feedback is very positive and encouraging.

2) **ARE THERE ANY PLANS TO USE THE INVENTION IN A PRODUCT?** *Give Product/Program name m milestone dates if known. Has this invention been identified as a program deliverable?*

This proposed invention is being used to implement ftMRA feature for MR Core Segment LEO 1 release (scheduled for [redacted].)

3) **WHAT ARE THE PLANS OR DESIRES TO PUBLISH?** *It is absolutely critical to identify the earliest possib public disclosure of the invention for legal reasons. This may include publication, installation of prototype, trade show etc. GEMS can lose the right to patent an invention by premature public disclosure.*

A limited external clinical evaluation of the working prototype is schedule for early [redacted] There will be abstract submission for ISMRM 2002 to demonstrate the advantage (robustness and ease of use) of the techniques fc various ce3DMRA and post contrast T1 (liver) imaging applications.

4) **DESCRIBE ANY KNOWN RELEVANT COMPETITOR ACTIVITY** – *Are any competitors working on solutions t the same problem? Have any competitors addressed the same problem?*

[redacted]

5) **WAS THIS INVENTION DEVELOPED IN THE COURSE OF A PROJECT WHICH WAS FUNDED IN PART BY AN ENTITY OTHER THAN GE?** *Has any work been done, for example, with Government funding, universit collaboration, even if such funding was provided indirectly, as via CRO?*

No

6) **WHAT IS THE EARLIEST TANGIBLE DOCUMENTATION OF THIS INVENTION?** *Is it a lab notebook engineering report, etc., or this disclosure document? If not this document, please provide a reference and a date.*

The earliest result of this work has been disclosed in the weekly execution control meeting for ASAP group around [redacted]

7) **HOW MUCH DIFFICULTY WOULD A COMPETITOR EXPERIENCE IN TRYING TO DESIGN AROUND THIS INVENTION?** *Are there many ways of relatively equal difficulty to solve the problem, or is the invention a unique solution in terms of benefit and simplicity?*

[redacted]